REMARKS

Claims 26-43 are presently pending in the case.

Claim provisionally rejections under judicially created doctrine of Double Patenting

The Examiner provisionally rejected claims 31-34 and 39-43 under the judicially created doctrine of double patenting as being unpatentable over the claims of pending US Patent Application 10/245,705. Since the present case is otherwise in condition for allowance, the present case should be allowed to issue and the double patenting issue should be taken up in the pending application.

The Examiner also rejected claims 31-33 and 39-42 under the judicially created doctrine of double patenting as being unpatentable over claims 1-11 and 13-16 of US Patent 6,358,530. Claim 1 of US Patent 6,358,530 recites "a dispersibility-enhancing amount of a physiologically-acceptable, water-soluble polypeptide." Accordingly, the claims are distinct. In addition, the claims of 6,358,530 do not anticipate the present claims, as suggested by the Examiner. The claims of 6,358,530 do not recite, for example, the insulin composition of claims 31 and 39 or the amorphous particles recited in claim 39. Withdrawal of the rejection is requested.

History of parent application

This application is a continuation of co-pending U.S. Patent Application Serial No. 08/668,036, now US Patent 6,685,967. The presently pending claims are identical to the issued claims in 08/668,036 except that "in the range from 0.1 μm to 5 μm" has been replaced with "below 10 μm".

US Patent Application 08/668,036 (now US Patent 6,685,967), the parent of the present case, was finally rejected by the Examiner. Applicant appealed the final rejections and the rejections were overturned by the Board of Patent Appeals and Interferences. The present claims are identical to the issued claims in 08/668,036 except that "in the range from 0.1 μm to 5 μm" has been replaced with "below 10 μm", as stated above.

The below chart shows the present claims and the issued claims in the parent case and highlights the differences between the claims. The chart also shows the Examiner's rejections of the claims that were overturned by the Board.

Currently pending claims (differences highlighted)	**Issued claims in 08/668,036 (differences highlighted)**	**Rejection in 08/668,036 that was overturned by the Board of Patent Appeals and Interferences**
26. A method for preparing a stable, dry powder insulin composition, said method comprising: dissolving insulin in an aqueous buffer at a concentration in the range from 0.01% to 1% to form a solution; and spray drying the solution to produce substantially amorphous particles having an average size **below 10 μm.**	15 (now 1). A method for preparing a stable, dry powder insulin composition, said method comprising: dissolving insulin in an aqueous buffer at a concentration in the range from 0.01% to 1% to form a solution; and spray drying the solution to produce substantially amorphous particles having an average size **in the range from 0.1 μm to 5 μm.**	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
27. A method as in claim 26, wherein the insulin is dissolved in a aqueous buffer together with a pharmaceutical carrier, wherein a dry powder having insulin present in individual particles at from 5% to 99% by weight is produced upon spray drying.	16 (2). A method as in claim 1, wherein the insulin is dissolved in a aqueous buffer together with a pharmaceutical carrier, wherein a dry powder having insulin present in individual particles at from 5% to 99% by weight is produced upon spray drying.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
28. A method as in claim 27, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.	17 (3). A method as in claim 2, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
29. A method as in claim 28, wherein the pharmaceutical carrier is a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin and trehalose.	18 (4). A method as in claim 3, wherein the pharmaceutical carrier is a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin and trehalose.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)

30. A method as in claim 28, wherein the pharmaceutical carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.	19 (5). A method as in claim 3, wherein the pharmaceutical carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696) Further in view of Chien (5,042,975) and/or Markussen (4,946,828)
31. An insulin composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include insulin present at from 20% to 80% by weight in a pharmaceutical carrier material, wherein the particles have an average size **below 10 µm.**	20 (6). An insulin composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include insulin present at from 20% to 80% by weight in a pharmaceutical carrier material, wherein the particles have an average size **in the range from 0.1 µm to 5 µm.**	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
32. An insulin composition as in claim 31, wherein the composition is substantially free from penetration enhancers.	21 (7). An insulin composition as in claim 6, wherein the composition is substantially free from penetration enhancers.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
33. An insulin composition as in claim 31, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.	22 (8). An insulin composition as in claim 6, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
34. An insulin composition as in claim 31, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.	23 (9). An insulin composition as in claim 6, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696) Further in view of Chien (5,042,975) and/or Markussen (4,946,828)

35. A method for preparing a stable, dry powder insulin composition, said method comprising: providing an aqueous solution of insulin and a pharmaceutical carrier dissolved in an aqueous buffer, wherein the insulin is present at 0.01% to 1% by weight and comprises from 20% to 80% of the total weight of insulin and pharmaceutical carrier in the solution; and spray drying the solution to produce amorphous particles comprising both the insulin and the pharmaceutical carrier having an average size below 10 μm and a moisture content below 10%.	26 (10). A method for preparing a stable, dry powder insulin composition, said method comprising: providing an aqueous solution of insulin and a pharmaceutical carrier dissolved in an aqueous buffer, wherein the insulin is present at 0.01% to 1% by weight and comprises from 20% to 80% of the total weight of insulin and pharmaceutical carrier in the solution; and spray drying the solution to produce amorphous particles comprising both the insulin and the pharmaceutical carrier having an average size **in the range from 0.1 μm to 5 μm** and a moisture content below 10%.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
36. A method as in claim 35, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.	27 (11). A method as in claim 10, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
37. A method as in claim 36, wherein the carbohydrate carrier is selected from the group consisting of mannitol, raffinose, lactose, malto dextrin and trehalose.	28 (12). A method as in claim 11, wherein the carbohydrate carrier is selected from the group consisting of mannitol, raffinose, lactose, malto dextrin and trehalose.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
38. A method as in claim 36, wherein the carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.	29 (13). A method as in claim 11, wherein the carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)

39. (Previously presented) An insulin composition for pulmonary delivery, said composition comprising: a dry powder of individual amorphous particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight, have an average particle size **below 10 μm**, and have a moisture content below 10%.	30 (14). An insulin composition for pulmonary delivery, said composition comprising: a dry powder of individual amorphous particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight, have an average particle size **in the range from 0.1 μm to 5 μm**, and have a moisture content below 10%.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
40. An insulin composition as in claim 39, wherein the particles consist essentially of the insulin and the pharmaceutical carrier.	31 (15). An insulin composition as in claim 14, wherein the particles consist essentially of the insulin and the pharmaceutical carrier.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
41. An insulin composition as in claim 39, wherein the composition is substantially free from penetration enhancers.	32 (16). An insulin composition as in claim 14, wherein the composition is substantially free from penetration enhancers.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
42. An insulin composition as in claim 39, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.	33 (17). An insulin composition as in claim 14, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
43. An insulin composition as in claim 39, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.	34 (18). An insulin composition as in claim 14, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696) Further in view of Chien (5,042,975) and/or Markussen (4,946,828)

A copy of the Board's decision has been included with the response of April 21, 2005 for the Examiner's convenience.

Current rejections

The Examiner rejected claims 31-34 and 39-43 under 35 USC 103(a) as being obvious over Platz (5,354,562) alone or in combination with one or more of Chien (US 5,042,975), Markussen (US 4,946,828), Hansen (4,614,730), JP 56 138 110, or JP 56 138 111. The rejections are not believed to be proper in view of the Board of Patent Appeals and Interferences decision discussed above.

Conclusion

The Examiner is respectfully requested to consider the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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